JUL 1 5 2010

510(k) Summary

Proprietary Name: Sapiens™ Tip Location System also known as evGuide™ Tip Location System

Device Trade name: Sapiens™ Tip Location System (TLS)

Product Classification: Class II, 21 CFR §880.5970
LJS - Accessory to Percutaneous, Implanted, Long-Term Intravascular Catheters
General Hospital

Applicant name: Romedex International Srl 58 Aleea Arubium, Bucharest, 022944 Romania, +1.650.209.4838, info@romedex.com, www.romedex.com

Contact person: Sorin Grunwald Ph.D., MBA, 175 Colorado Ave, Palo Alto, CA 94303, sorin@romedex.com, Tel: +1.650.209.4838, Fax: +1.650.887.0348

Preparation Date: June 4, 2010

Predicate Devices: K091324 - Sherlock 3CG Tip Positioning System
K032613 - Transvenous Pacemaker Placement Assist Device
K973371 - Conduction Anesthesia Kit
K843263 - Arrow-Johans ECG Adaptor

Indications for Use: The Sapiens™ Tip Location System (TLS) is indicated for guidance and positioning of central venous catheters such as PICCs, CVCs, implantable ports, and hemodialysis catheters. The Sapiens™ TLS provides real-time catheter tip location information by using the patient's cardiac electrical activity. Sapiens™ TLS is indicated for use as an alternative method to chest X-ray and fluoroscopy for central venous catheter tip placement confirmation in adult patients.

Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm, and in central venous catheterization procedures performed through femoral or saphaneous vein access which change the presentation of the P wave. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.

Device Description: The Sapiens™ TLS consists of the following elements: sterile electrical adaptor, ECG module and cable, laptop running Sapiens™ TLS software, label printer (optional), and remote control (optional). A stylet or a guidewire inserted in a central venous catheter can be connected to the Sapiens™ TLS system via the Sapiens™ TLS Electrical Adaptor establishing a direct electrical connection to the catheter distal tip for ECG signal measurement. A different ECG signal measurement method – the column of saline method – can be used by connecting the Sapiens™ TLS Electrical Adaptor to the Arrow-Johans Adaptor, by connecting the Arrow-Johans Adaptor to any central venous catheter and by injecting saline solution into the catheter lumen through the Arrow-Johans Adaptor, thus establishing electrical conductivity to the distal tip of the catheter. When the central venous catheter or its associated stylet or guidewire is connected to Sapiens™ TLS, the Sapiens™ TLS laptop screen displays skin ECG signals and endovascular electrograms acquired at the location of the distal tip of the catheter. The waveforms provided by Sapiens™ TLS can be used for guiding and positioning of the central venous catheter. These ECG waveforms can be printed using an optional label printer to document the catheter tip location for the patient's file.

Bench Top Safety & Performance Tests: Verification and validation tests have been performed in accordance with Design Controls per 21 CFR §820.30.

Bench top testing has been performed side-by-side with available predicate devices which has demonstrated substantial equivalence of Sapiens™ TLS to the respective predicate devices. The following tests were performed: a) electrical impedance testing and b) ECG waveform accuracy tests.

Summary of Non-clinical Data:

Non-clinical studies were performed which have demonstrated safety and efficacy of Sapiens™ TLS using Electrical Adaptor, good correlation between bench top and in-vivo data, and substantial equivalence with predicate devices. The following tests were performed: a) ECG waveform accuracy comparison with a commercially available ECG monitor, b) ECG waveform accuracy comparison with the Conduction Anesthesia Kit (K973371) and c) system usability and validation testing.

Summary of Clinical Data:

To date, Sapiens™ TLS has been used in Europe for central venous catheter guidance and positioning in five major hospital centers on more than 350 adult patients (ages 19-96) of both genders for placing several types of central venous catheters: PICCs, CVCs, implantable ports, hemodialysis catheters, and tunneled catheters. Several types of users including nurses and physicians have used Sapiens™ TLS for different clinical procedures, e.g., oncology, anesthesia, patient monitoring in the ICU, hemodialysis in different clinical settings: in the operating room, in outpatient clinics and at the bedside.

Side-by-side comparisons with available predicate devices were performed which demonstrated substantial equivalence of Sapiens™ TLS to the respective predicate devices.

In the two analyzed subsets of 362 patients (332 patients from a prospective, multicenter, non-controlled study and 30 patients form a human factors/ usability study), the catheter tip placement using Sapiens™ TLS at the desired location was confirmed with chest X-ray or fluoroscopy in 97% of the cases. No adverse events or complications have occurred.

Summary of Technological Characteristics Compared to Predicate Devices

The subject Sapiens™ TLS Electrical Adaptor combines design features, materials and technological characteristics of marketed predicate devices including the Transvenous Pacemaker Placement Assist Device (K032613) and Conduction Anesthesia Kit (K973371) such as: a) a sterile, insulated, electrically conductive wire of very low electrical resistance; b) a distal end alligator clip to connect to stylets and guidewires; c) a proximal end connector which can be connected to an ECG cable or to an ECG connection switch. When compared to the Conduction Anesthesia Kit, the Sapiens™ TLS Electrical Adaptor has simplified the design of the device by removing the switch box. When compared to Transvenous Pacemaker Placement Assist Device, the Sapiens™ TLS Electrical Adaptor has simplified the design of the device by removing the connection box.

The Sapiens™ TLS Electrical Adaptor may be connected to the ECG pin of the predicate Arrow-Johans Adaptor (K843263) using an ECG cable which allows for the saline conduction method of ECG measurement. Use of the Sapiens™ TLS Electrical Adaptor with the Arrow-Johans Adaptor does not require any modifications of design features, materials, or technological characteristics of the marketed predicate device.

Additionally, the subject Sapiens™ TLS System combines design features, components and technological characteristics of the predicate device Sherlock 3CG Tip Positioning System (K091324) but uses only cardiac electrical signal detection to provide real-time catheter tip location information. The subject Sapiens™ System does not use a passive magnet like the predicate device.

Any differences between technological features of the subject and predicate devices do not raise new questions of safety or efficacy of the subject Sapiens™ TLS device.

Summary of Substantial Equivalence:

The Sapiens™ TLS has the same intended use and similar indications for use as the commercially available Sherlock 3CG Tip Positioning System (K091324), Transvenous Pacemaker Placement Assist Device (K032613), Conduction Anesthesia Kit (K973371), and Arrow-Johans ECG Adaptor (K843263). Additionally, clinical and non-clinical performance testing has demonstrated that any differences in technological characteristics do not raise new issues of safety or effectiveness when compared to the aforementioned predicate devices. Therefore, the Sapiens™ TLS meets the requirements for substantial equivalence to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUL 28 2010

Dr. Sorin Grunwald, Ph.D.
US FDA Agent for Romedex International, Srl
175 Colorado Avenue
Palo Alto, California 94303

Re: K093775
Trade/Device Name: Sapiens™ TLS
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: June 5, 2010
Received: June 7, 2010

Dear Dr. Grunwald:

This letter corrects our substantially equivalent letter of July 15, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093775 Not known at this time ____

Device Name: Sapiens™ TLS

Indications for Use:

The Sapiens™ Tip Location System (TLS) is indicated for guidance and positioning of central venous catheters such as PICCs, CVCs, implantable ports, and hemodialysis catheters. The Sapiens™ TLS provides real-time catheter tip location information by using the patient's cardiac electrical activity. Sapiens™ TLS is indicated for use as an alternative method to chest X-ray and fluoroscopy for central venous catheter tip placement confirmation in adult patients.

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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Page __ of ___
(Posted November 13, 2003)

Richard C. Chapman 7/20/10
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093775